In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

ERIC KOONCE,	*	
	*	No. 21-1560V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	
	*	Filed: January 3, 2024
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Laura J. Levenberg, Muller Brazil, Dresher, PA, for petitioner;
Sarah B. Rifkin, United States Dep't of Justice, Washington, DC, for respondent.

RULING FINDING ENTITLEMENT TO COMPENSATION[1]

Eric Koonce alleges that an influenza ("flu") vaccine harmed him and seeks compensation via three avenues. First, Mr. Koonce argues that he developed a neurologic disorder, Guillain-Barré syndrome, and seeks the benefit of a presumption of causation via the Vaccine Injury Table. Second, Mr. Koonce supports a claim that the flu vaccine was the cause-in-fact of his Guillain-Barré

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Ruling will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

syndrome with the report from an expert. Third, Mr. Koonce maintains that the flu vaccine was the cause-in-fact of a different condition, Bell's palsy.

The Secretary contends that Mr. Koonce is not entitled to compensation. The Secretary's position is advanced by arguments from attorneys. The Secretary has not presented evidence from an expert he retained for this litigation.

As discussed below, Mr. Koonce is entitled to compensation. Thus, the case will proceed to damages.

I. Events in Mr. Koonce's Life[2]

In October 2018, Mr. Koonce was 50 years old. His medical history does not contribute to resolving his claim for compensation. He received a flu vaccine on October 17, 2018. Exhibit 1.

On November 8, 2018, Mr. Koonce reported that he had numbness in his face and left facial droop, starting one day earlier. Exhibit 3 at 57. The doctor in the emergency room diagnosed Mr. Koonce as suffering from Bell's palsy. He was prescribed a tapered course of prednisone. Id. at 60.

In a follow-up with his primary care doctor (Christine Dacier), Mr. Koonce essentially repeated this history. Exhibit 2 at 33 (Nov. 14, 2018). Dr. Dacier also diagnosed Bell's palsy and recommended another appointment in a week. Id.

In the return appointment, Mr. Koonce told Dr. Dacier that he "continued to improve." Exhibit 2 at 31 (Nov. 20, 2018). Movement in his face was increased. Dr. Dacier stated that Mr. Koonce is "medically stable to return to work as a pilot." Id.

On about November 23, 2018, Mr. Koonce developed numbness and weakness in his feet and ascending his legs for which he sought treatment in an

[2] Mr. Koonce's medical history is presented relatively summarily. For a more complete account, see Resp't's Second Am. Report, filed Mar. 24, 2023, at 3-10, and Pet'r's Mot. for a Ruling on the Record, filed July 17, 2023, at 2-4.

emergency room on November 30, 2018. Exhibit 4 at 29. He stated the weakness started after he completed his course of steroids. A physical examination, however, did not detect any weakness in his lower extremities. Yet, Mr. Koonce had decreased sensation from his feet to his mid-shins. Id. at 30. Mr. Koonce was admitted to the hospital.

Mr. Koonce remained in the hospital for four days. A neurologist, John Khoury, examined Mr. Koonce. Dr. Khoury stated "Hopefully this is just a steroid induced Neuropathy but given the recent [Bell's] palsy it is possible this is a Miller Fisher Variant of GBS." Id. at 444. Dr. Khoury recommended that if Mr. Koonce's symptoms worsened or if he lost his ankle reflexes, Mr. Koonce should have a lumbar puncture.

Whether Mr. Koonce's symptoms did worsen, or he lost his ankle reflexes is not clear. Regardless, Mr. Koonce underwent a lumbar puncture on December 1, 2018. The results showed an elevated protein level without an elevated blood count. Exhibit 4 at 108. Doctors interpreted these results as "consistent with GBS." Id. at 10, 250, 311. Mr. Koonce continued to report that he felt weak, although the examination did not detect weakness or a loss of reflexes. Id. at 10. The doctors ordered intravenous immunoglobulin therapy ("IVIG") and Mr. Koonce had four sessions while in the hospital. After 4 days of IVIG, Mr. Koonce's symptoms improved.

At discharge, Mr. Koonce's diagnosis was the Miller Fisher syndrome. Id. at 10-12 (Dec. 4, 2018 discharge report). He was instructed to follow-up with his primary care physician.

Mr. Koonce returned to Dr. Dacier and reported his recent diagnosis of GBS. Mr. Koonce also described new symptoms, including fever, chills, fatigue. Exhibit 2 at 28 (Dec. 20, 2018). Mr. Koonce also reported continued numbness from the knees down.

Next, Mr. Koonce saw a neurologist, Richard Buckler. Dr. Buckler stated Mr. Koonce's "symptoms and examination [were] suggestive of Guillain-Barré syndrome in view of the paresthesias, [left-sided] facial droop and depressed deep

tendon reflexes in the upper extremities and an elevated CSF protein of 210." Exhibit 31 at 8 (Dec. 26, 2018).

Mr. Koonce returned to see the neurologist who had cared for him in the hospital, Dr. Khoury, on January 7, 2019. Exhibit 5 at 9. Dr. Khoury memorialized Mr. Koonce's previous complaints and hospitalization. Dr. Khoury noted that after IVIG treatment, Mr. Koonce's bilateral leg numbness had improved. Mr. Koonce denied any weakness and reported some numbness in his toes. Mr. Koonce walked normally and could stand on either foot without difficulty. Dr. Khoury assessed Mr. Koonce with "post viral GBS." Id. at 10. Dr. Khoury stated that because Mr. Koonce was "doing great," "no additional therapy [was] needed at this time." Id. Dr. Khoury cleared Mr. Koonce "to work without restriction." Id.

In April 2019, Mr. Koonce saw both his neurologist (Dr. Khoury) and his primary care doctor (Dr. Dacier). He was not having neurologic problems. See Exhibit 5 at 7, Exhibit 2 at 20. But, in May 2019, Mr. Koonce told his other neurologist, Dr. Buckler, that his numbness had worsened. Exhibit 31 at 12.

Mr. Koonce sought another opinion regarding his neurologic problems from Eric Lancaster at Penn Medicine on June 21, 2019. Exhibit 6 at 11. (As discussed below, the views of Dr. Lancaster contribute to the determination that Mr. Koonce is entitled to compensation.) Dr. Lancaster obtained a history from Mr. Koonce, in which Mr. Koonce informed Dr. Lancaster he had ascending numbness but "Never became weak" and "Still had reflexes." Id. at 12. In the first hospitalization, Mr. Koonce had a high protein. Apparently, Mr. Koonce was unclear about the diagnosis "Miller Fisher vs. GBS." Id.

Through electronic medical records, Dr. Lancaster reviewed various documents, including the "Abington hospital admission records. Discharge diagnosis was GBS" and Dr. Khoury's notes from January 7, 2019 and April 1, 2019 in which Dr. Khoury diagnosed GBS. Exhibit 6 at 13.

For current problems, Mr. Koonce stated that "his feet are still tingling and numb and he feels it up to his knees. No convincing symptoms in hands. Face never became weak since the first attack of Bell's Palsy." Id. at 18.

Dr. Lancaster's impression was that: "Mr. Koonce has bell's palsy and then had an acute neuropathy. Since there was an LP showing high protein and normal CSF cell counts, it is hard to come up with any different cause tha[n] GBS for his symptoms. It does seem like he had a limited form of GBS with much less disability that is usual for GBS." Id. at 19. Dr. Lancaster did not recommend any additional immune therapy. Dr. Lancaster recommended some tests for other causes of neuropathy.

Dr. Lancaster ended his report with comments about the vaccine. Dr. Lancaster wrote: "We discussed vaccine causation. I disclosed that I have consulted for the vaccine injury compensation program. He is considering whether to apply for this program. I discussed my understanding of how these programs work." Id.

After some intervening medical appointments, Mr. Koonce visited with Dr. Lancaster via telemedicine on February 12, 2021. Exhibit 6 at 17. A primary purpose was to discuss vaccinations, particularly the Covid-19 vaccination. Dr. Lancaster wrote: "I would probably avoid a repeat flu shot but would not avoid other vaccines." Id. at 19-20.

The parties have not identified other medical records contributing to determining whether Mr. Koonce is entitled to compensation. See Pet'r's Mot. at 4 (concluding with Dr. Lancaster's Feb. 12, 2021 visit); Resp't's Second Amended Rep. at 10 (same).

II. Procedural History

Mr. Koonce began this case by submitting his petition on July 9, 2021. During the summer 2022, the parties attempted to resolve the case but were not successful. Pet'r's Status Rep., filed Aug. 5, 2022.

The Secretary recommended against compensation. The primary argument was that Mr. Koonce did not meet the definition of Guillain-Barré syndrome as set forth in the regulations because he did not have weakness in his limbs. Resp't's Rep., filed Sep. 23, 2022, at 10. The Secretary also maintained that Mr. Koonce failed to support any off-Table claim as he lacked a report from an expert.

Mr. Koonce obtained a report from Joseph S. Jeret, a neurologist. Exhibit 14. Dr. Jeret asserted that Mr. Koonce "satisfies the Vaccine Injury Table criteria for GBS, but [not] the criteria for Miller-Fisher Syndrome." Exhibit 14 at 7. Dr. Jeret opined that the flu vaccine was the cause-in-fact of Mr. Koonce's Bell's palsy. Id. at 7-9.

The Secretary presented another report on March 13, 2023. The Secretary stated that "he will not continue to defend this case during further proceedings on entitlement before the Office of Special Masters, and requests a ruling on the record regarding petitioner's entitlement to compensation." Resp't's First Am. Report, filed Mar. 13, 2023, at 1. The Secretary's analysis was confusing. The Secretary maintained that Mr. Koonce "has not met his burden of proof under the Vaccine Act for the reasons set forth in his initial Rule 4(c) Report." Id. at 11. However, one reason the Secretary originally gave for declining to compensate Mr. Koonce was that Mr. Koonce did not have an expert report. While that statement was true in September 2022, it was not accurate in March 2023.

The evidence, including Dr. Lancaster's reports and Dr. Jeret's report, were discussed in a March 14, 2023 status conference. The Secretary was directed to file an amended report. Order, issued March 14, 2023.

The second amended report again recommended against an award of compensation. The Secretary addressed three claims. First, the Secretary argued that Mr. Koonce did not establish he suffered from Guillain-Barré syndrome as defined in the qualifications and aids to interpretation. Second Am. Report at 10-12. The key point was the lack of limb weakness. Id. at 11, citing 42 C.F.R. § 100.3(c)(15)(ii)(A). Thus, according to the Secretary, Mr. Koonce was not entitled to a presumption of causation.

Second, the Secretary argued that Mr. Koonce did not establish that he was entitled to compensation for his Bell's palsy. The Secretary contended that Mr. Koonce's Bell's palsy did not last sufficiently long to meet the severity requirement. The Secretary did not challenge Mr. Koonce's satisfaction of the Althen prongs for Bell's palsy. Id. at 13-14.

Third, the Secretary argued that Mr. Koonce did not establish that he was entitled to compensation for his Guillain-Barré syndrome as an off-Table claim. The key point was inconsistencies in Dr. Jeret's report. Id. at 15. In this context, the Secretary did not discuss the reports from Dr. Lancaster. The Secretary also did not challenge Mr. Koonce's satisfaction of the Althen prongs for Guillain-Barré syndrome.

After being ordered to file a brief regarding entitlement, Mr. Koonce did so on July 17, 2023. The Secretary did not submit a response within the time permitted by the Vaccine Rules. Thus, Mr. Koonce's motion is ready for adjudication.

III. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing a special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with the dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

IV. Analysis Part One – on-Table GBS

Petitioners who establish that they received a vaccine listed on the Vaccine Table, suffered an injury listed on the Vaccine Table, and this injury occurred in the amount of time after a vaccine listed on the Vaccine Table are presumed to have established that the vaccine caused the injury. See Shalala v. Whitecotton, 514 U.S. 268, 270 (1995). Of these subsidiary components, the sole disputed item is whether Mr. Koonce suffered Guillain-Barré syndrome.

Congress authorized special masters to award compensation based upon "medical records" or "medical opinion." 42 U.S.C. § 300aa–13(a)(1). Medical records may be sufficient to establish that a vaccinee suffered an injury listed in the Vaccine Table. See Harrington v. Sec'y of Health & Hum. Servs., 139 Fed. Cl. 465, 469 (2018) (denying motion for review, in part, because petitioner did not establish that he suffered from GBS); Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (looking first to determine whether a treating doctor diagnosed a child-vaccinee with an encephalopathy before turning to reports from retained experts); Keith v. Sec'y of Health & Hum. Servs., 55 Fed. Cl. 791, 797 (2003) (denying motion for review and stating that "in the absence of clear, definitive medical records establishing this injury, a [petitioner] as actual manifestations of Brachial Neuritis").

Here, ample evidence shows that Mr. Koonce's diagnosis of Guillain-Barré syndrome appears in "medical records" created by doctors who treated him.

- Doctors at Abington Hospital interpreted the results of the spinal tap as "consistent with GBS." Exhibit 4 at 10, 250, 311.
- The discharge report from Abington Hospital stated that Mr. Koonce suffered from a subtype of Guillain-Barré syndrome, Miller Fisher syndrome. Exhibit 4 at 10-12 (Dec. 4, 2018 discharge report).
- Neurologist Richard Buckler stated Mr. Koonce's "symptoms and examination [were] suggestive of Guillain-Barré syndrome. Exhibit 31 at 8 (Dec. 26, 2018).
- Neurologist John Khoury assessed Mr. Koonce with "post viral GBS." Exhibit 5 at 10 (Jan. 7, 2019).

- Neurologist Eric Lancaster wrote, "it is hard to come up with any different cause tha[n] GBS for his symptoms." Exhibit 6 at 13 (June 21, 2019).

In short, three neurologists diagnosed Mr. Koonce with Guillain-Barré syndrome. Dr. Khoury saw Mr. Koonce while he was hospitalized. Dr. Buckler saw Mr. Koonce shortly after he was discharged. Dr. Lancaster had the benefit of reviewing electronic medical records. The Secretary has not argued that any of these three doctors were mistaken or unreliable. Taken together, these reports constitute convincing evidence that Mr. Koonce had Guillain-Barré syndrome.

Despite the reports from doctors who treated Mr. Koonce, the Secretary argues that he did not satisfy the regulatory definition of Guillain-Barré syndrome. In relevant part, the definition requires "Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs." 42 C.F.R. § 100.3(c)(15)(ii)(A); see also 80 Fed. Reg. 45132, 45145 (notice of proposed revisions to Vaccine Injury Table) (July 29, 2015).

Although not spelled out, the Secretary's position seems to be that "weakness" must be found by a doctor. Mr. Koonce's subjective report of weakness (exhibit 4 at 29) apparently does not satisfy the Secretary. However, according to Dr. Jeret, a lack of objective confirmation is "not uncommon" because "bedside testing can easily miss minor weakness." Exhibit 14 at 6. This opinion is not rebutted.

Dr. Jeret's opinion was that Mr. Koonce "satisfies the Vaccine Injury Table criteria for GBS." Exhibit 14 at 7. Thus, Dr. Jeret is an additional neurologist who has stated that Mr. Koonce suffered from Guillain-Barré syndrome.

To counter the opinions from four neurologists, the Secretary has not presented any evidence such as a report of a doctor retained for this litigation. The Secretary has not proposed any other diagnosis that would explain Mr. Koonce's numbness and elevated protein at the end of November 2018. Although the Secretary does not bear the burden to propose an alternative diagnosis, the lack of evidence proposing an alternative diagnosis undermines the Secretary's stance.

Accordingly, Mr. Koonce has demonstrated that he suffered from Guillain-Barré syndrome. He has also satisfied the other elements to be awarded compensation for Guillain-Barré syndrome.[3]

V. Analysis Part 2: off-Table Bell's Palsy

As to whether Mr. Koonce should receive compensation for his Bell's palsy, the parties differ. Through Dr. Jeret, Mr. Koonce alleges that the flu vaccine caused him to develop Bell's palsy. Exhibit 14 at 7-8. The Secretary argued that the Bell's palsy resolved so quickly that Mr. Koonce cannot satisfy the Vaccine Act's severity requirement. Second Am. Rep. at 13. The Secretary did not contend that Mr. Koonce's evidence failed to fulfill the Althen prongs. In reply, Mr. Koonce identified a June 21, 2019 medical record in which Dr. Lancaster stated that the left side of Mr. Koonce's face showed "'subtle synkinesis.'" Pet'r's Mot. at 19, quoting Exhibit 6 at 12.

Here, although Mr. Koonce's Bell's palsy was not severe, the Bell's palsy has lasted more than six months. See Exhibit 14 at 5 (Dr. Jeret's report, linking the subtle facial synkinesis to Bell's palsy). Thus, Mr. Koonce has demonstrated that he fulfills the Vaccine Act's severity requirement.

Other than severity, the Secretary did not interpose any reason to deny compensation for Bell's palsy. Thus, Mr. Koonce is entitled to compensation. See Vaccine Rule 4(c)(1) (requiring the Secretary to set forth "a full and complete statement of its position as to why an award should or should not be granted").

VI. Conclusion

Mr. Koonce has demonstrated that he is entitled to compensation for Bell's palsy and Guillain-Barré syndrome. An order regarding the process for quantifying the compensation to which he is entitled will be issued shortly.

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[3] Given that Mr. Koonce established his claim for compensation based upon the Vaccine Injury Table, an analysis of Mr. Koonce's alternative theory that the flu vaccine was the cause-in-fact of his Guillain-Barré syndrome is superfluous.

Any questions regarding this ruling may be directed to my law clerk, Debbie Chu, at (202) 357-6360.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master